KENAS
Delivering Trust

KENYA
ACCREDITATION
SERVICE

SDE-PR-01-02

Formulation of Accreditation Scopes Procedure

Table of Contents

1 Background Information 2
1.1 Purpose 2
1.2 Scope 2
1.3 Role(s) and Responsibility 2
2 Terms and Definitions 2
2.1 Acronyms and Abbreviations 2
2.2 Definition of Terms 3
3 Process Detail 3
3.1 Scope accreditation of a CAB 3
3.2 Definition of the scope of accreditation 3
3.3 Application for Accreditation 8
4 Associated Documents 8
5 Revision/ Amendment Records 10

1 Background Information

1.1 Purpose

The procedure provides for how the scopes for KENAS accreditation schemes are formulated in order to allow for clear statements that will avoid ambiguity and confusion to clients. In addition, the procedure provides for scope definition of accreditation in order to allow for an effective and harmonized application among KENAS schemes in relation to the relevant international Standards.

1.2 Scope

The procedure sets out how the scope of accreditation for the various schemes shall be defined.

1.3 Role(s) and Responsibility

Role	Responsibility
Process owner	All Accreditation Staff
Reviewer	Accreditation Managers
Recommender	CMCI/CMLA
Approval	CEO
Compliance	All KENAS Staff

2 Terms and Definitions

For the purpose of this manual, the following terms and definitions shall apply in addition to those given in ISO/IEC 17000 and the KENAS Act CAP496.

2.1 Acronyms and Abbreviations

CEO	Chief Executive Officer
CMCI	Chief Manager Certification and Inspection
CMLA	Chief Manager Laboratories
CAB	Conformity Assessment Body
ISO	International Organization for Standardization
IEC	International Electrotechnical Commission
QMS	Quality Management System
EMS	Environmental Management System

FSMS	Food Safety Management System
OHSAS	Occupational Health and Safety Assessment Series
NACE	National Association of Corrosion Engineers International
CB	Certification Body

2.2 Definition of Terms

2.2.1 Scope

A formal and precise statement of the activities to which a Conformity Assessment Body is accredited for.

3 Process Detail

3.1 Scope accreditation of a CAB

3.1.1 The scope of accreditation of a CAB is the official and detailed statement of the activities for which the CAB is accredited. In ISO/IEC 17011, it is required that the accreditation body shall provide an accreditation certificate to the accredited CAB which shall provide a brief indication of, or reference to, the scope of accreditation.

3.1.2 Scope of accreditation is the Specific conformity assessment activities for which accreditation is sought or has been granted.

3.1.3 The formulation and assessment of the scope of accreditation represents the core of the accreditation process. The role of KENAS is to ensure (to an adequate degree of confidence) that the CAB has the competence to offer the service defined in the scope.

3.1.4 KENAS offers fixed and flexible scope under the established accreditation schemes as applicable.

3.2 Definition of the scope of accreditation

3.2.1 Testing and Calibration

3.2.1.1 The scope of accreditation can be clearly defined by parameters such as described in the table below(this table covers testing and calibration)

Testing Laboratory	**Calibration Laboratory**	**Medical / Veterinary Laboratory/Point Of Care Testing (POCT)**
Testing field	**Calibration field** (e.g. dimensional	**Medical field**

Testing Laboratory	Calibration Laboratory	Medical / Veterinary Laboratory/Point Of Care Testing (POCT)
(e.g. environmental testing or mechanical testing)	measurements; Force, Mass, Torque, Pressure, etc.)	Medical Laboratory field (e.g. clinical chemistry, haematology)
Type of test/ techniques (e.g. mass spectrometry or hardness testing). This may include the equipment or the equipment can be indicated independently.	-	**Examination technique** (e.g. IR spectrophotometry) This may include the equipment or the equipment can be indicated independently.
Test object or product/ Matrix (e.g. automotive components); Matrices (e.g. tap water)	**Calibration objects** (e.g. gauge blocks, Balances, Resistance Thermometers, etc.)	**Specimen**: This is the biological sample (e.g. whole blood, serum, body fluid)
Test parameter (when appropriate) (e.g. hardness)	**Measurand** i.e. Quantity, property (e.g. length, Mass, Temperature, Pressure)	**Components / Analytes** (e.g. CO2) or related groups of analytes (e.g. liver function) *
Internal method with Reference to standardized method (e.g. ISO 14577-1:2003)	**Internal Calibration procedure with Reference to standardized procedure** (when appropriate and applicable)	**Internal examination procedure with Reference to standardized procedure** (when appropriate and applicable)
Measurement range where applicable	**Measurement range** **Calibration and Measurement**	**Measurement range** where applicable

Testing Laboratory	Calibration Laboratory	Medical / Veterinary Laboratory/Point Of Care Testing (POCT)
	Measurement uncertainity **Capability (CMC)** – This implies the calibration measurement capability expressed as an expanded expressed as follows; Measurement Point / Range ± expanded uncertainty; (The expanded uncertainty is expressed as the standard uncertainty of measurement multiplied by a coverage factor *k*=2, corresponding to a 95% confidence level. The unit of uncertainty shall be the same as that of the measurand, unless a range is used, in which case the uncertainty shall be expressed as a percentage which can further be calculated. In specialized fields like electrical additional parameters may be required and hence need to be specified e.g. frequency of applied voltage.	
Test Location	**Calibration Site**	**Test Location**

3.2.1.2 The methods/calibration or examination procedures are usually an important reference to give in the scope and may be specific or generic and can be based on standard methods or laboratory developed methods:

a) Non-standard or laboratory-developed methods are developed by the laboratory itself, other parties, or adapted from standard methods and validated.
b) Standard methods are developed by a standardization body or other well-established organizations whose methods are generally accepted by the technical sector in question.

3.2.1.3 In describing the scope of the laboratory, it is relevant in some cases to give both a reference to a standardised method as well as an internal method reference (in the quality management system).

3.2.1.4 The scope of accreditation shall be described in the schedule that is annexed to the certificate of accreditation.

3.2.2 Scoping for inspection bodies

The scope of accreditation of inspection bodies shall be clearly defined by parameters such as described below:

Field of Inspection (e.g. Product Design, Products (materials or equipment), Installation, Plant, Premises, Processes, Services and Surveys). Where the field is general like physical inspection; further information will be need for the product or service to which the inspection activity is being carried out.
Type and Range of inspection (e.g. In-service Inspection or Inspection of new products).
Codes / Regulations /Methods/standards (e.g. Directives, local Regulations, Standard Specs, Internal procedures).
Inspection Location being the location where the inspection activity is carried out.

3.2.3 Scoping for Certification bodies

The scope of accreditation of certification bodies shall be clearly defined by parameters such as described below whose details are further provided in additional Criteria documents for the various management systems i.e. QMS, EMS, OHSAS, FSMS:

Management System	Product	Person
Type of Certification **Management System sub-scope** (e.g. QMS, EMS, FSMS, OHSAS, etc.)	**Scheme** This is the scheme to which the product certification rides (e.g. Global Gap, Kenya Gap, etc.)	**Scheme** This is the scheme to which the product certification rides (e.g. Kenya Registered Nurse)
Standard, Normative reference	**Standard, Normative reference**	Regulatory requirement
Industry Sectors as per IAF Codes (These are the codes as defined in the listing as per the KENAS guidance documents and IAF ID 1	**Product** Indicates the product(s)/ process(es) that are certified under that scheme. (e.g. Green peas, Tea, Fish, etc.)	-
NACE Codes The codes are as defined in the KENAS guidance documents or in NACE coding system version 2	**Code / regulations/std**. (applies to the particular industry, national, regional or international, requirements to which the scheme is developed.	**Code / regulations/std**. (applies to the particular profession, industry, national, regional or international, requirements to which the scheme is developed

3.2.4 Scoping for Proficiency Testing

The scope of accreditation for PT providers shall be clearly defined by parameters such as described below:

Schemes that the proficiency testing provider is competent to provide;
Type/Field e.g. Environmental, Mechanical Clinical
Measure and/Protocol Provide the detail to which the PT is based and if in-house, the reference
Equipment / Artefact

For testing and inspection fields the equipment and/or matrix maybe specified, but for Calibration, the Artefact will be of more importance
Standard This is the standard applied in reference to the PT program. It may be a National requirement hence a regulation, etc.
Parameter The analyte or component(s) provided for evaluation by the program
Measurement Capability

3.2.5 Scoping for Verification and validation bodies

The scope of accreditation of certification bodies shall be clearly defined by parameters such as described below whose details are further provided in additional criteria documents for the various validation or verification schemes

Verification or validation activity Identification of the activity if verification or validation
Verification or validation scheme This is the scheme to which the verification or validation scheme rides (e.g GHG Emissions)
Standards/Regulations/Codes Applies to the particular profession, industry, national, regional or international, requirements to which the scheme is developed

3.3 Application for Accreditation

The Application for Accreditation for Conformity Assessment Bodies (ACC-FM-06) shall provide for fields in which the CAB can populate the required information in order to provide for a clear scope.

4 Associated Documents

Ref	Document Identifier	Document Title
1.	ISO/IEC 17011	Requirements for accreditation bodies accrediting

Ref	Document Identifier	Document Title
		conformity assessment bodies
2.	ISO/IEC 17020	Conformity assessment; requirements for the operation of various types of bodies performing inspection
3.	ISO 15189	Medical laboratories - Particular requirements for quality and competence
4.	ISO/IEC 17021-1	Conformity assessment - Requirements for bodies providing audit and certification of management systems
5.	ISO/IEC 17024	Conformity assessment - Requirements for bodies providing certification of persons
6.	ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
7.	ISO/IEC 17043	Proficiency testing by inter-laboratory comparison - Development and operation of proficiency testing schemes
8.	ISO/IEC 17065	Conformity assessment – Requirements for bodies operating product certification systems
9.	ISO/IEC 17029	Conformity assessment — General principles and requirements for validation and verification bodies
10.	ILAC G 18	Formulation of scopes for use by accreditation bodies
11.	IAF MD 17	Witnessing Activities for The Accreditation Of Management Systems Certification Bodies
12.	IAF ID1	QMS scopes of Accreditation
13.	ILAC P14	ILAC Policy for Uncertainty in Calibration
14.	ILAC 28	Guidelines for Formulation of Scopes of accreditation for inspection Bodies
15.	ACC-PR-07	Management and Reporting of Assessments

Ref	Document Identifier	Document Title
16.	ACC-PR-03	Sampling during assessments and internal audits
17.	ACC-FM-06	Application for Accreditation of Conformity Assessment bodies

5 Revision/ Amendment Records

Date	Ver	Revised By	Reason for Revision
10/10/2022	01	SDE	Newly developed/formatted document
30/06/2025	02	QRM	Systematic Review of QMS Documentation